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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,992

12/07/2005

Ricky R. Ruschke

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EXAMINER

FRISTOE JR, JOHN K

ART UNIT

PAPER NUMBER

3753

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,992	Applicant(s) RUSCHKE ET AL.	
	Examiner JOHN K. FRISTOE JR	Art Unit 3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-124 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 14-18, 21-23, 25-31, 34-37, 43, 48, 49, 54, 62-64, 78-81, 87, 89 and 93-97 is/are allowed.
- 6) ☒ Claim(s) 2, 65, 82, 83 and 92 is/are rejected.
- 7) ☒ Claim(s) 20 and 84-86 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/16/07, 3/13/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1,3,4,6-13,19,24,32,33,38-42,44-47,50-53,55-61,66-77,88 and 98-124.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group D in the reply filed on 3/13/2008 is acknowledged. The traversal is on the ground(s) that there was no lack of unity in the corresponding PCT and the explanation of the special technical feature is insufficient. This is not found persuasive because the excessive number of claims within the instant Application as well as the myriad of combinations claimed rendered the Application burdensome.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1, 3, 4, 6-13, 19, 24, 32, 33, 38-42, 44-47, 50-53, 55-61, 66-77, 88 and 98-124 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/13/2008.

Information Disclosure Statement

3. The information disclosure statements filed 10/16/2007 and 3/13/2008 are acknowledged by the examiner

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 2, 65, 82, and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,634,434 (Marino, Jr. et al.). Marino, Jr. et al. disclose a needlefree access device comprising a housing (26), an inlet (15), a base (23), a generally cylindrical inside surface

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(within element 26), a valve member (29, 33), an outlet (16), a central body (20), a helical shape (28), wherein the central body (20) fits against the inside surface (within element 26), a helical flow path (30), wherein the device (figure 3) is suitable for transferring medical fluids, a piston (29), a wedge member (start of helix 28) in figure 3), and an IV bag (13).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,634,434 (Marino, Jr. et al.) in view of U.S. Pat. No. 6,802,490 (Leinsing et al.). Marino, Jr. et al. disclose a needlefree access device comprising a housing (26), an inlet (15), a base (23), a generally cylindrical inside surface (within element 26), a valve member (29, 33), an outlet (16), a central body (20), a helical shape (28), wherein the central body (20) fits against the inside surface (within element 26), a helical flow path (30), wherein the device (figure 3) is suitable for transferring medical fluids, a piston (29), a wedge member (start of helix 28) in figure 3), and an IV bag (13) but lacks the inlet having a luer taper. Leinsing et al. teaches a medical connector having an inlet (28) with a luer taper. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needless access device of Marino, Jr. et al. by adding a luer taper to the inlet as taught by Leinsing et al. in order to connect a luer fitting.

Allowable Subject Matter

8. Claims 5, 14-18, 21-23, 25-31, 34-37, 43, 48, 49, 54, 62-64, 78-81, 87, 89 and 93-97 are allowed.

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9. Claims 20 and 84-86 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John K. Fristoe Jr. whose telephone number is (571) 272-4926.

The examiner can normally be reached on Monday-Friday, 7: 00 a.m-4: 30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John K. Fristoe Jr./
John K. Fristoe Jr.
Examiner
Art Unit 3753

JKF